Claims

Sub D1

1. *Helicobacter pylori* protein in a substantially purified form, capable of being obtained from an *H. pylori* membrane fraction, and whose molecular weight after electrophoresis on a 10% polyacrylamide gel in the presence of SDS appears of the order of 54, 50, 32-35 or 30 kDa; provided that when the molecular weight is 54 kDa, the protein does not react with an anti-catalase antiserum.

2. Protein according to Claim 1, whose apparent molecular weight is of the order of 54 kDa and which is capable of being obtained by a process in which:

(i) the *H. pylori* bacteria are extracted with 1% n-octyl ß-D glucopyranoside, followed by centrifugation;

(ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;

(iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;

(iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium;

(v) the membrane fraction is subjected to an anion-exchange chromatography on a Q-Sepharose column in a 0 - 0.5 M NaCl gradient, followed by washing in 1 M NaCl;

(vi) the fraction eluted at the start of washing in 1 M NaCl is recovered and it is subjected to an anion-exchange chromatography on a DEAE-Sepharose column, in a 0 - 0.5 M NaCl gradient; and

(vii) the fraction eluted in 0.1 - 0.25 M NaCl is recovered.

Sub D1 Cont'd.

3. Protein according to Claim 1, whose apparent molecular weight is of the order of 50 kDa and which is capable of being obtained by a process in which:

(i) the *H. pylori* bacteria are extracted with 1% n-octyl ß-D glucopyranoside, followed by centrifugation;

(ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;

(iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;

(iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium;

(v) the membrane fraction is subjected to an anion-exchange chromatography on a Q-Sepharose column in a 0 - 0.5 M NaCl gradient, followed by washing in 1 M NaCl;

(vi) the fraction eluted at the start of washing in 1 M NaCl is recovered and it is subjected to an anion-exchange chromatography on a DEAE-Sepharose column, in a 0 - 0.5 M NaCl gradient; and

(vii) the fraction eluted in 0.3 - 0.4 M NaCl is recovered.

4. Protein according to Claim 3, which has as N-terminal sequence the amino acid sequence as shown in SEQ ID NO 1.

5. Protein according to Claim 1, whose apparent molecular weight is of the order of 30 kDa and which is capable of being obtained by a process in which:

(i) the *H. pylori* bacteria are extracted with 1% n-octyl ß-D glucopyranoside, followed by centrifugation;

(ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;

(iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;

(iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium;

(v) the membrane fraction is subjected to an anion-exchange chromatography on a Q-Sepharose column in a 0 - 0.5 M NaCl gradient;

(vi) the fraction eluted in 0.28 - 0.35 M NaCl is recovered and it is subjected to an anion-exchange chromatography on a DEAE-Sepharose column, in a 0 - 0.5 M NaCl gradient; and

(vii) the fraction corresponding to the direct eluate is recovered (absence of NaCl).

6. Protein according to Claim 1, whose apparent molecular weight is of the order of 32-35 kDa and which is capable of being obtained by a process in which:

(i) the *H. pylori* bacteria are extracted with 1% n-octyl ß-D glucopyranoside, followed by centrifugation;

(ii) a bacterial pellet is recovered and it is treated with lysozyme and subjected to sonication, followed by centrifugation;

(iii) a centrifugation pellet is recovered and it is subjected to washing with 20 mM Tris-HCl buffer pH 7.5, followed by centrifugation;

(iv) the membrane fraction consisting of the centrifugation pellet is recovered and it is resuspended in aqueous medium, advantageously in carbonate buffer pH 9.5;

(v) the suspension obtained in (iv) is centrifuged at about 200,000 x g and the supernatant is recovered;

(vi) the pH of the supernatant obtained in (v) is reduced to about pH 7, advantageously by dialysing against phosphate buffer pH 7;

(vii) the preparation obtained in (vi) is subjected to a cation-exchange chromatography on an SP-Sepharose column in a 0 - 0.5 M NaCl gradient, advantageously in a phosphate buffer pH 7; and

(vii) the fraction eluted in 0.26 - 0.31 M NaCl is recovered.

7. *Helicobacter* protein or a polypeptide derived from the protein by fragmentation and/or mutation, in a substantially purified form, which is capable of being recognized by an antiserum raised against a protein according to claim 1.

8. Pharmaceutical composition for the prevention or treatment of an *H. pylori* infection, which comprises as active ingredient a protein or a polypeptide according to claim 1.

9. Pharmaceutical composition for the prevention or treatment of an *H. pylori* infection, which comprises as active ingredient a protein or a polypeptide according to claim 7.

10. Monospecific antibody capable of recognizing a protein or a polypeptide according to claim 1.

11. Monospecific antibody capable of recognizing a protein or a polypeptide according to claim 7.

12. Pharmaceutical composition intended for the prevention or treatment of an *H. pylori* infection, which comprises as active ingredient a monospecific antibody according to claim 10.

13. Pharmaceutical composition intended for the prevention or treatment of an *H. pylori* infection, which comprises as active ingredient a monospecific antibody according to claim 11.

14. Diagnostic method which makes it possible to detect the presence of *Helicobacter* in a biological sample, according to which the biological sample is brought into contact with an antibody according to claim 10 so that an immune complex forms, the unbound material is optionally removed and the immune complex formed between the sample and the antibody is detected.

15. Diagnostic method which makes it possible to detect the presence of antibodies to *Helicobacter* in a biological sample, according to which the biological sample is brought into contact with a polypeptide of claim 7 so that an immune complex forms, the unbound material is optionally removed and the immune complex formed between the sample and the polypeptide is detected.

16. Process for the purification of a protein or of a polypeptide according to claim 1 from a biological sample, according to which the biological sample is subjected to an affinity chromatography using a monospecific antibody according to claim 10.